



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,434	07/18/2002	Michael B Thornton	PI-0137 USN	3714
22428	7590	09/08/2005	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			SAIDHA, TEKCHAND	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

<b>Application No.</b>	<b>Applicant(s)</b>	
10/069,434	THORNTON ET AL.	
<b>Examiner</b>	<b>Art Unit</b>	
Tekchand Saidha	1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1.  The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a)  The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2.  The Notice of Appeal was filed on 08 August 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3.  The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

- (a)  They raise new issues that would require further consideration and/or search (see NOTE below);
- (b)  They raise the issue of new matter (see NOTE below);
- (c)  They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d)  They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4.  The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7.  For purposes of appeal, the proposed amendment(s): a)  will not be entered, or b)  will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 3-9, 11 and 51.

Claim(s) withdrawn from consideration: 13, 15, 27 and 28.

**AFFIDAVIT OR OTHER EVIDENCE**

8.  The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9.  The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10.  The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11.  The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

\_\_\_\_\_

12.  Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_

13.  Other: \_\_\_\_\_

**Advisory Action**

1. The amendment filed August 8, 2005 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and WILL NOT BE ENTERED because: the proposed amendment to claims raises new issues that would require further consideration and/or search. Amended claim 3(b) recite 'amino acid sequence of at least about 20 contiguous amino acids of SEQ ID NO: 1....', for example. Such a fragment of 20 amino acids will require further sequence search, and the claims language 'at least about', rejection under 112 second.
2. Applicants' amendment-after final, response and notice of appeal filed August 8, 2005, is acknowledged.
3. The status of the claims remains the same as indicated in the 'Final Rejection', and is reproduced here.
4. Claims 3-9, 11 & 51 [SEQ ID NO: 4 encoding polypeptide of SEQ ID NO: 1] were pending and under consideration.
5. **New Matter added to claims only** - [New Matter rejection]

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 6, 7, 8 & 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's addition [new matter] of 'wherein the fragment

has carbonic anhydrase activity or where the fragment has immunological activity of carbonic anhydrase' in claims 3, 6, 7, 8 & 9, either directly or in a dependent manner, is not supported by the original disclosure. Applicants are required to cancel the new matter in reply to this office action.

The recitation of "has carbonic anhydrase activity" in Claim 3 (upon which Claims 6-9 depend) does not have support in the specification as filed. Applicants point to page 79 of the specification which includes Table 2 which describes SEQ ID NO: 1 as providing support for the instant amendment. However, this portion of the specification is merely describing the activity of the **closest homolog not of the polypeptide of SEQ ID NO: 1**. This passage does not support the amendment that SEQ ID NO: 1 or any fragment thereof has carbonic anhydrase activity or immunological activity of carbonic anhydrase'.

## 6. **Written Description**

Claims 11 & 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of polynucleotide molecules [90% similarity to SEQ ID NO: 4] or wherein polynucleotide(s) (or DNA) encode polypeptide sequence(s) which are is 90% or 95% identical to the amino acid sequence of SEQ ID NO : 1, with no defined function associated with it.

The specification describes SEQ ID NO: 1 as human lyase referred to as 'HLYA', encoded by the DNA sequence of SEQ ID NO: 4. The specification does not contain any disclosure or description of the structure and function of all DNA/polypeptide sequences that are 90% or 95% identical to SEQ ID NO: 4 or 1, or wherein such a DNA would likely encode polypeptide(s) having lyase activity. Lyases are a class of enzyme that catalyze the cleavage of C-C, C-O, C-N, C-S, C-(halide), P-O, or other bonds without hydrolysis or oxidation to form

two molecules, at least one of which contains a double bond (see instant specification, page 1, lines 10-12). These lyases based upon the functional cleavage will utilize distinct substrate(s) and may be decarboxylases, carbonic anhydrase, l-phenyl ammonia lyase(s), S-hydroxynitrile lyase(s), pectate lyase(s), hydroperoxide lyase(s), etc. However, the specification fails to describe SEQ ID NO: 1 to have any specific lyase activity. Further, the specification as filed does not describe size of the immunogenic or size or function of any biologically active fragment. The genus of polynucleotides or polypeptides that comprise these DNA molecules is a large variable genus with the potentiality of encoding many different proteins with no function, or polypeptides with no associated regulatory or biochemical function. Therefore, many functionally unrelated DNA or polypeptide molecules are encompassed within the scope of these claims, including partial DNA sequences or polypeptide fragments. The specification discloses only 3 species each of the polypeptide [SEQ ID No. 1-3] and 3 species of the encoding polynucleotide [SEQ ID No. 4-6] of the claimed genus, which has not been disclosed to be representative of each other, and is therefore insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus of polypeptides/polynucleotides having 90% or 95% similarity and their fragments and using these sequences in the preparation of vector, host cell and for making the polypeptide recombinantly. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicants' arguments:

Applicants argue citing Table 2 of the instant specification that SEQ ID NO: 1 is **59%**, from residue M1 to residue A239, to human carbonic anhydrase I [GenBank ID g179793]. Data from BLIMPS, MOTIFS and PROFILESCAN analyses provide further corroborative evidence that SEQ ID NO: 1 is a carbonic anhydrase. Based upon the above data, Applicants argue that they

have clearly indicated thus, that the claimed sequence and other sequences disclosed in the specification are carbonic anhydrases.

Applicants' arguments are considered but not found persuasive, because this portion of the specification is merely describing the activity of the closest homolog not of the polypeptide of SEQ ID NO: 1. There is no clear indication in the specification that SEQ ID NO: 1 or any fragment thereof has carbonic anhydrase activity or immunological activity of carbonic anhydrase'.

Applicants' attention is drawn to protein sequences having about **62%** sequence homology to the instant polypeptide of SEQ ID NO: 1, wherein these proteins have been designated gamma-phosphatase and beta-phosphatase [See the enclosed sequence search alignments between Applicants' SEQ ID NO: 1 with sequence 8 of issued patent 5,891,700 & sequence 4 of issued patent 5,604,094]. Clearly, Applicants protein have been identified with enzymes such as carbonic anhydrase (59% homology), have also been identified with enzymes such as gamma-phosphatase and beta-phosphatase (62% homology). Therefore, in the instant situation wherein the protein in question is assigned a broader function covering a range of enzymes [such as lyases] based upon sequence homology to other proteins or enzymes, and narrowing the broader function to a specific one [such as a carbonic anhydrase] based upon the later findings by others [see Applicants' arguments, page 13, showing that the disclosed polypeptide sequence of SEQ ID NO:1 is 100% identical to amino acids 1-242 of the polypeptide disclosed by **Lehtonen et al. (2004)** and termed carbonic anhydrase XIII or CA XIII"].

Further, the instant claims have no activity limitation. Thus lacking structure to function relationship. The rejection is maintained.

## 7. ***Enablement Rejection***

Claims 3, 6-9, 11 & 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid (or polynucleotide) sequence of SEQ ID NO : 4 encoding a specific lyase (?) of SEQ

Art Unit: 1652

ID NO : 1, does not reasonably provide enablement for : any fragment, [biologically active or immunogenic] of SEQ ID NO : 1 or 4; or that encoding a protein having 90% or 95% homology to SEQ ID NO : 1 or a nucleic acid having 90% similarity to SEQ ID NO: 4.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) [*Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim. The factors most relevant to this rejection are [the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

The specification provides guidance and examples for making an isolated polynucleotide comprising SEQ ID NO: 4 and the encoded lyase (non-specific) having a sequence of SEQ ID NO : 1. However, the specification does not teach specific fragment molecules of these sequences or does not teach the specific structural/catalytic amino acids and the structural motifs essential for protein activity/function which cannot be altered. The state of the art as exemplified by Attwood et al. [Comput. Chem. 2001, col. 54(4), pp. 329-39] is such that “..we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given the knowledge only of its sequence or structure in isolation” (see abstract and the entire publication). Further Ponting [Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29] states that “...predicting function by homology is a qualitative,

rather than quantitative process and requires particular care to be taken, due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domain in proteins" (see abstract and the entire publication).

The standard of meeting enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed polynucleotide is enormous and entails selecting specific nucleotides to change (deletion, insertion, substitution or combination thereof) in a polynucleotide to make a claimed polynucleotide and determining by assays whether the polypeptide has activity. The specification does not provide guidance with respect to the specific structural/catalytic amino acids and the structural motifs essential for enzyme structure/function which must be preserved. Thus, searching for the specific nucleotides to change (deletion, insertion, substitution or combination thereof) in a polynucleotide to make polynucleotide that is at least 90% identical to a polynucleotide comprising nucleotides of SEQ ID NO: 4 [or polypeptide sequence of SEQ ID No.1], and transforming host cell or organism [including human] using the isolated nucleic acid(s) is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polypeptide has activity is extremely low since no guidance is provided with respect to the structural motifs essential for enzyme structure and activity/function which must be preserved. Further, the disclosed meaning of the phrase 'biologically active' [specification], page 12, lines 21-22] is a protein having structural, regulatory **or** biochemical functions. These lyases based upon the functional cleavage will utilize distinct substrate(s) and may be decarboxylases, carbonic anhydrase, l-phenyl ammonia lyase(s), S-hydroxynitrile lyase(s), pectate lyase(s), hydroperoxide lyase(s), etc. However, the specification fails to describe SEQ ID NO: 1 to have any specific lyase activity.

Determining the biological function(s) would be highly unpredictable as no specific lyase function or enzyme assay using a particular substrate and associated with SEQ ID NO: 1 is described in the instant specification. Likewise, "immunologically active" or "immunogenic" refers to the capability of the natural, recombinant, or synthetic HLYA, or of any oligopeptide thereof, to induce a specific immune response in appropriate animals or cells and to bind with specific antibodies, and such a fragment(s) is neither taught or guidance provided to one skilled in the art to prepare one from the sequences provided.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific catalytic amino acids and structural motifs essential for activity/function which must be preserved in order to alter or modify the sequences as claimed. Without such a guidance, the experimentation left to those skilled in the art is undue.

Applicants' Arguments:

Applicants argue that claims as amended, i.e., claim 3 has been amended to recite 'a biologically active fragment of SEQ ID NO: 1, wherein the fragment has carbonic anhydrase activity' and an immunogenic fragment comprising at least about 10 amino acids of SEQ ID NO: 1, wherein the fragment has immunological activity of carbonic anhydrase.' Claim 11 has been amended to recite 'a naturally occurring polynucleotide comprising a polynucleotide sequence at least 90% identical to a polynucleotide sequence of at least about 60 contiguous nucleotides Of SEQ ID N0:4.' With regard to the limitation "a biologically active fragment of SEQ ID NO:1, wherein the fragment has carbonic anhydrase activity," as recited in claim 3, the specification describes an exemplary assay for carbonic anhydrase activity. In addition, assays for measuring carbonic anhydrase activity are well known in the art. Because carbonic anhydrases have been studied and are well known in the art, one skilled in the art would know how to identify "specific catalytic amino acids" and/or structural motifs essential for activity/function which must be

preserved" without undue experimentation.

Applicants arguments have been considered and found not persuasive. Indeed assays are known for carbonic anhydrase as well as the numerous LYASES as well as one skill in the art can identify specific catalytic domain and/or structural motifs essential for activity/function which must be preserved" without undue experimentation. However, based upon the guidance provided in the instant specification one of skill in the art would still be searching to discover the specific lyase function of the protein of SEQ ID NO: 1. Applicants have failed to provide any activity data, more specifically showing that their SEQ ID NO: 1 is a carbonic anhydrase. Applicants have referenced or suggested a variety of alternate enzyme assay methods based upon the close homologies of these enzymes to the 3 different lyases of SEQ ID Nos. 1-3. These alternate enzymes bearing a reasonably higher or equal % of sequence homology. Some of the alternate enzyme names include ornithine decarboxylase II, human adenylate kinase, carbonic anhydrases of various types [see entire page 25 of the instant specification], or a pyridoxal dependent decarboxylases [see table 3, reference to SEQ ID NO: 2]. This coupled with the Examiner's sequence search indicating the existence of protein sequences having about **62%** sequence homology to the instant polypeptide of SEQ ID NO: 1, wherein these proteins have been designated gamma-phosphatase and beta-phosphatase [See the enclosed sequence search alignments between Applicants' SEQ ID NO: 1 with sequence 8 of issued patent 5,891,700 & sequence 4 of issued patent 5,604,094]. In close situations such as these, the actual experimental data becomes vital in establishing the true identity of the lyase. Applicants have not provided any activity or experimental data or evidence to show the true identity of SEQ ID NO: 1 or 2 or 3; [SEQ ID NO: 2 & 3 are not under consideration] and the specific enzyme activity associated with it. Without a clear-cut guidance, the experimentation left to those skilled in the art is unreasonable and undue.

8.

**Utility**

Claims 3-9, 11 & 51 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicants disclose a nucleic acid sequences (SEQ ID NO: 4) encoding the amino acid sequence of SEQ ID NO: 1. Based on reasonable sequence homology as per Examiner's sequence search discussed earlier the protein appears to belong to a family of Lyases, which is a generic asserted utility. Lyases belong to a family of enzymes which utilizes varying substrates and are involved in distinct biological processes. It is nearly impossible from sequence homology to determine specific function. Sequence homology may give clues to predictable function. However, in the instant case there cannot be any specific match between the Applicants' generic claimed function and SEQ ID NO: 1. The protein of SEQ ID NO: 1 has a more likely probability to be any of the member of lyase family. Even accepting the plausible utility of being a lyase, one of ordinary skill in the art would not know which is a substrate for the enzyme. The specification does not disclose a specific function of the polypeptide of SEQ ID NO: 1 and any activity data, its relationship to any disease, or any specific real world use. The specification describes generic functions for the protein, nucleic acid, and antibodies. The utility of the nucleic acid is said to be used in a method to detect a human gene and to recombinantly make the polypeptide of SEQ ID NO: 1 which neither the gene or the polypeptide associated with a specific use or a disease. It appears that the main utility of the polypeptide and nucleic acid is to carry out further research to identify the biological function and possible diseases associated with said function. A more than one page list of diseases associated with the lyase of SEQ ID NO: 1 is given on pages 38-39 of the instant specification. However, it is impossible to determine which of these diseases are truly associated the

polypeptide of SEQ ID NO: 1. Substantial utility defines a real world use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicants Arguments:

Applicants traverse the utility rejection and argue that the claimed invention is fully supported by pointing to the entire disclosure and further cite the recent works of Lehtonen et al. [2004] to support the carbonic anhydrase function to the protein of SEQ ID NO: 1.

This argument is not found to be persuasive, and is explained in item 8, above.

Note: It must be pointed out that Applicants have not responded to many of the key issues pertaining to the prior written description, enablement as well as utility rejections.

9. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claims 3, 6-9 & 51 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3, lines 9-10, recites the limitation ‘wherein the fragment has immunological activity of carbonic anhydrase’. The claims are indefinite because it is unclear how an ‘immunogenic fragment’ would have ‘immunological activity of carbonic anhydrase’. A protein fragment can have the activity of carbonic anhydrase.

It is suggested to amend claim 3 (d), to “an immunogenic fragment consisting of .....amino acids of SEQ ID NO: 1.”; to reconsider this rejection. The ‘length of the fragment’ is important in overcoming this rejection or not.

Claims 6-9 & 51 are included in the rejection for failing to correct the defect present in the base claim(s).

10. ***Claim Rejections - 35 USC § 102 (previous)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 6-7, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowe et al. Lowe et al. [Gene, 93: 277-283 (1990)] teach a carbonic anhydrase [or a lyase], which is 62.4% similar to Applicants' polypeptide of SEQ ID NO: 1 [sequence search alignment, previously provided] and has several 5 or more identical amino acids. Claim 3 is directed to an immunogenic fragment comprising at least about 10 amino acids of SEQ ID NO: 1. DNA encoding the protein is also taught. The reference reads upon Applicants' immunogenic fragment comprising at least 10 amino acids. Additional limitation 'wherein the fragment has immunological activity of CA' is indefinite and does not carry any weight. Further, the at least about 10 amino acids need not be contiguous, and such a fragment is disclosed in the carbonic anhydrase sequence of Accession No. CRHU1. The corresponding DNA (Accession No. M33987) sequence (see Figures 1 & 2) is also taught. The reference also teaches method of making the carbonic anhydrase by expression in host cell and recovering the protein. The claims are written so broadly as to be anticipated by the reference.

11. **35 U.S.C. 102(e) - new**

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is

determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Accession No. AAB59589 [USP 6160090, filing date 1993]. Accession No. AAB59589 in US Patent 6160090 is designated as a human carbonic anhydrase [see the enclosed sequence search alignment between Accession No. AAB59589 and Applicants' SEQ ID NO: 1]. Applicants' SEQ ID NO: 1, residues 191-200 are exact match to Accession No. AAB59589 residues 188-197, and reads on the claim 3 limitation 'of at least about 10 amino acids of SEQ ID NO: 1'. The reference anticipates the claim.

12. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tekchand Saidha  
Primary Examiner, Art Unit 1652  
Recombinant Enzymes, E03A61 Remsen Bld.  
400 Dulany Street, Alexandria, VA 22314  
Telephone : (571) 272-0940  
August 24, 2005